Remarks

Claims 21-46 and 48-61 are pending.

The rejections under 35 U.S.C. §112

Claims 21-46 and 48-61 were rejected for lack of written description because of the recitation of the phrase "such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering."

The Applicants respectfully traverse this rejection.

It is well settled that a written description need not describe the subject matter claimed in the same words as are used in the claims. All that is necessary is that the specification reasonably convey that the inventors had possession of the claimed subject matter (*Fiers v. Revel*, 984 F.2d 1164, 1170, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993)) or clearly allow persons of ordinary skill in the art to recognize that the applicants invented what is claimed (*Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991)). In particular, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims" (*Eiselstein v. Frank*, 52 F.3d 1035, 1038, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995)). See also *All Dental Prodx, LLC v. Advantage Dental Products, Inc.*, 309 F. 3d 774, 779, 64 USPQ2d 1945, 1948 (Fed. Cir., 2002) ("The failure of the specification to specifically mention a limitation that later appears in the claims is not a fatal one when one skilled in the art would recognize upon reading the specification that the new language reflects what the specification shows has been invented.")

Although the exact words of the phrase at issue do not appear in the present specification, the specification describes the subject matter of the phrase at issue. In the

context of the present invention, the phrase at issue and the term "incidence" have the same meaning.[1] See the Amendment filed December 14, 2006, page 10:

> The specification consistently uses a reduction in "incidence" to refer to a reduction in the number or percentage of cows showing clinical symptoms of mastitis after vaccination as compared to before vaccination.

There is no question that the specification provides a written description, in fact a verbatim written description, of the term "incidence." See, e.g., the specification, at page 19, lines 20-22: "Field evaluations were made by comparing clinical incidence of mastitis caused by *Mycoplasma bovis* following herd vaccination to the base line herd incidence prior to vaccination." See also page 21, lines 11-12: "Following vaccination of a significant portion of the herd at Site 1 and Site 2, the incidence of mycoplasma was greatly reduced."

Since the phrase at issue has the same meaning as "incidence," and the specification provides a written description for "incidence," the specification also provides a written description for the phrase at issue.

Moreover, even if the relation described above between "incidence" and the phrase at issue is not considered, the specification would still provide a written description for the phrase at issue. The specification repeatedly describes the administration of the recited vaccine to bovine animals, followed by a description of such beneficial effects of the vaccine as reduction in levels of infection, lack of clinical mastitis events, and lack of confirmed cases of mastitis in vaccinated animals. The specification also states that the vaccine decreases the effect of *M. bovis* infections on milk production, weight gain, and animal health.

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[1] The phrase at issue was added to the present claims in the Amendment dated December 14, 2006 to emphasize the meaning of the term "incidence" since that term had been interpreted in the previous Office Action in a manner inconsistent with its use in the specification and the art (see the Amendment dated December 14, 2006, pages 10-12).

See, e.g., Example 5, on page 18-20. In Example 5, a herd suffering from endemic mastitis infection (page 18, lines 27-28) was vaccinated. The numbers of clinical (i.e., showing symptoms) *Mycoplasma bovis* infections before and after vaccination were compared and a dramatic decrease was noted.

See page 19, lines 20-31:

> Field evaluations were made by comparing clinical incidence of mastitis caused by *Mycoplasma bovis* following herd vaccination to the base line herd incidence prior to vaccination. Results were as follows:
>
> Pre Vaccination Base Line Incidence:
> 155 confirmed positive clinical Mycoplasma bovis infections
>
> Post Vaccination Herd Incidence:
> 1st year following vaccination:
> 24 confirmed positive clinical Mycoplasma bovis infections
> 2nd year following vaccination:
> 1 confirmed positive clinical *Mycoplasma bovis* infection.

See also Example 6, at pages 20-21, particularly the passage at page 21, lines 4-15, which reads as follows:

> A vaccine was prepared using antigen from 3 biotypes of *M. bovis* (A, B and C) as described in Example 3 above and was used to vaccinate cattle at both Site 1 and Site 2 according to the regime described in Example 5. Vaccinations began in mid-September, 1999. The incidence of Mycoplasma mastitis was monitored by independent laboratory testing for the presence of Mycoplasma in any animal determined by farm personnel to have mastitis.
>
> Following vaccination of a significant portion of the herd at Site 1 and Site 2, the incidence of mycoplasma was greatly reduced. From January 1, 2000 to July 18, 2000, there were only 10 animals reported positive for *Mycoplasma bovis* at each site. This reduction in the incidence of *Mycoplasma* positive mastitis cows was regarded as a significant reduction by the operators of Sites 1 and 2.

This passage describes a reduction in the number of animals with *Mycoplasma bovis* infections following vaccination. This reduction was recognized by farm personnel who determined whether the animals had mastitis. Although not explicitly stated, those farm personnel must have been evaluating the animals for clinical symptoms of mastitis. Thus, this passage clearly conveys the concept of the phrase at issue. That is, the number

of cows showing clinical symptoms of mastitis was less after as compared to before vaccination.

See also the specification at page 22, line 28, to page 23, line 1:

> Following the initiation of the vaccination regime for the herd in February, 2000, a veterinarian monitored the herd for the incidence of *M bovis*. The dairy reported in September 2000 that there were no confirmed cases of *Mycoplasma* in vaccinated animals, despite the continued challenge from the presence of confirmed, infected nonvaccinated animals.

Here the specification describes a reduction in "confirmed cases of *Mycoplasma*." It follows necessarily, even though not explicitly stated, that the number of cows showing clinical symptoms of mastitis decreased, since the number of cases of mastitis decreased.

See also the abstract: "These vaccines demonstrate no undesirable side effects and protect against *M. bovis* related disease, such as contagious mastitis ..." If the vaccines are protecting against contagious mastitis, they must be decreasing the numbers of cows showing clinical symptoms of mastitis.

The abstract also states: "The novel vaccines also lessen the effect of *M. bovis* infections on milk production, weight gain and animal health." Here, a reduction in several clinical symptoms (decreased milk production, lack of weight gain, and poor overall health) is described. This is reiterated at the sentence bridging pages 9 and 10, which explains that administration of the vaccines of the present invention leads to "a commercially beneficial effect that lessens the effect of *M. bovis* on milk production, weight gain or animal health."

See also page 22, lines 20-22: "[T]he vaccinated animals performed well as measured by days to market and rate of gain, both important indicators of a calf's health and well-being."

Examples 8 and 9, at pages 22-23, describe administration of the Applicants' vaccine leading to a decrease in cases of mastitis ("[T]here were no confirmed cases of Mycoplasma in vaccinated animals ..." (Example 8, page 22, lines 30-31); "There have

been no reported clinical mastitis events in vaccinated animals." (Example 9, page 23, lines 13-14)).

The numerous passages from the specification quoted above all describe a decrease in the number or percentage of cows showing observable ill effects (i.e., clinical symptoms) from mastitis infections. The Applicants submit that these passages reasonably convey that the Applicants had possession of the subject matter of the phrase "such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering." Accordingly, the specification provides a written description for that phrase.

In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 21-46 and 48-61 were rejected under the second paragraph of 35 U.S.C. §112 because of the phrase "whereby the incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering."

According to the Office Action, this phrase is unclear. The Office Action stated, at the paragraph bridging pages 4-5:

> It is unclear as to what the Applicant is referring? What clinical symptoms are reduced? Does a reduction in clinical symptoms necessarily mean that incidence of mastitis is reduced? A symptom of a disease or disorder can be reduced and the subject still has the disease or disorder. [underscoring in original]

The Applicants respectfully traverse this rejection.

The standard for finding a claim indefinite under the second paragraph of 35 U.S.C. §112 is very difficult to meet. A claim is indefinite only if it is "insolubly ambiguous." See *Xerox Corp. v. 3Com Corp.*, 458 F. 3d 1310, 1323, 80 U.S.P.Q. 2d 1916, 1927 (Fed. Cir. 2006):

> [W]e hold that claims 9 and 11 are "subject to construction" and are not "insolubly ambiguous." For that reason, those claims are not invalid for indefiniteness. *See Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1371 (Fed.Cir.2004) (holding that a claim will not be held invalid if the "meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree").

Case law holds that a claim is indefinite only if one skilled in the art would not understand what is claimed when the claim is read in light of the specification. *See, e.g., Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986) ("A decision on whether a claim is invalid under §112, 2d ¶, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification."). Furthermore, claims are not indefinite if one skilled in the art can determine whether a particular process is within the scope of the claims. *Application of Mercier*, 185 USPQ 774, 780, 515 F. 2d 1161, 1168 (CCPA 1975).

The comments in the Office Action indicate that the use of the word "symptoms" in the phrase at issue may have prompted this rejection ("What clinical symptoms are reduced? ... A symptom of a disease or disorder can be reduced and the subject still has the disease or disorder.").

The Applicants would like to point out that "symptom" is a common word with a well-understood meaning. Thus, its use does not make the claims so ambiguous that one skilled in the art would not understand what is claimed and its use certainly does not make the claims insolubly ambiguous. Moreover, as explained above in connection with the written description rejection, the specification provides many examples of what is meant by symptoms (e.g., decreased milk production, lack of weight gain, and poor overall health).

Given that "symptoms" has a well-understood meaning, and that the specification provides examples of symptoms, it cannot be held that the use of this word makes the claims indefinite. One skilled in the art would understand what is claimed and thus would be able to determine whether a particular process is or is not within the scope of the present claims. Determining whether the number or percentage of cows showing clinical

symptoms of mastitis is reduced after immunization as compared to before immunization could be done simply by counting cows with and without a particular symptom, before and after vaccination.

The Office Action asked: "Does a reduction in clinical symptoms necessarily mean that incidence of mastitis is reduced?" [underscoring in original] The answer is yes, since, as explained above in connection with the written description rejection, the meaning of incidence is the same as that of the phrase at issue here.

The Office Action also commented: "A symptom of a disease or disorder can be reduced and the subject still has the disease or disorder." The Applicants submit that such a comment is not relevant to the present claims since the present claims do not require the complete elimination of a disease or disorder.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The time for responding to the Office Action was set for June 21, 2007. Enclosed is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon LLP's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

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